

Arguments/Remarks

Claims 1-5 and 7 are pending, and presently stand rejected. Applicants have amended claim 1 to more clearly define patentable subject matter. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. 103

The Examiner has rejected claims 1-5 and 7 under 35 U.S.C. 103 as being obvious over Takaya et al (1985). Applicants disagree.

The Examiner has not established a *prima facie* case of obviousness. The Federal Circuit recently addressed obviousness of closely-related chemical structures in *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007). Specifically citing their decision of *In re Deuel*, 51 F3d 1552, the Court stated, "A known compound may suggest its homolog, analog, or isomer because such compounds 'often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties'." The Court clarified however, "that in order to find a *prima facie* case of unpatentability in such instances, a showing that the 'prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention' was also required."

The Court further held in *Takeda*, "Thus in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish a *prima facie* obviousness of a new claimed compound."

Still further, the CAFC has elucidated the obviousness factors for chemical structures in *Elsai v. Dr. Reddy's Laboratories* (533 F.3d 1353) (Fed. Cir. 2008). The CAFC discussed the *Graham* factors in new chemical composition cases, stating, "Post-KSR, a *prima facie* case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound."

It is therefore fundamental that in order to establish a *prima facie* case of obviousness for a chemical composition of matter, it is necessary to establish a lead compound from the prior art. It is further necessary to establish a showing that the prior art

would have suggested making the specific molecular modifications to the lead compound necessary in order to achieve the claimed invention.

In the present case, the Examiner has neither identified a "lead compound" from Takaya, nor identified a teaching in the art which would lead one of skill in the art to make the modifications to arrive at the claimed invention. In the absence of such an analysis, a *prima facie* case of obviousness has not been established.

As the Examiner states, the compounds of Takaya are different from the presently claimed compounds by virtue of an alkyl group in place of a hydrogen. Applicants have additionally amended the subject matter so that R<sub>2</sub> is phenyl or thiophenyl. Takaya discloses only a pyridil group at that molecular position.

Applicants respectfully request entry of the amendments to the claims and the specification and submit no new matter is added thereby. Should the Examiner have any questions, please contact the undersigned attorney.


However, if it is deemed that additional fees are required, the Commissioner is authorized to charge Deposit Account No. 504409 in the name of Novartis for any fees due.

In view of the above, an early Notice of Allowance is respectfully requested.

Should the Examiner have any questions, please contact the undersigned attorney.

Respectfully submitted,

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